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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/784,174 | 02/16/2001 | Joseph P. Steincr | 22903XA-T | 1443 |

29728 7590 12/15/2003

GUILFORD PHARMACEUTICALS C/O
FOLEY & LARDNER
3000 K STREET, NW
WASHINGTON, DC 20007-5143

EXAMINER

COOK, REBECCA

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1614

DATE MAILED: 12/15/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 09/784,174 | | STEINER ET AL. | |
| | Examiner | | Art Unit | |
| | Rebecca Cook | | 1614 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,6 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-6, 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The final rejection has been withdrawn and prosecution is reopened in view of the rejections that follow.

Claim Rejections - 35 USC § 112

Claims 5-6, 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5, 6 and 8, respectively, recite the phrase "an effective amount of a compound for treating alopecia or promoting hair growth in an animal in need thereof, wherein said compound is of formula" I, II and IV, respectively. The claims further recite "a second hair revitalizing agent." However, it is not clear if an effective amount of hair revitalizing agent is required and if said hair revitalizing agent treats alopecia or promotes hair growth or does something else. Furthermore, there is no antecedent basis in the claims for the recitations "a second hair revitalizing agent."

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 5-6 and 8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-23, 32 of copending Application No. 09/879,888. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Instant claim 5 recites

“A pharmaceutical composition which comprises:
(i) an effective amount of a compound for treating alopecia or promoting hair growth in an animal in need thereof, wherein said compound is of formula I...
(ii) a second hair revitalizing agent; and
(iii) a pharmaceutically acceptable carrier.”

In claim 5 the compound of formula I is an N linked ketone or diketone, when M is O. The compound is either an ester or amide, depending on whether A is O, NH or N-(C₁ –C₄) alkyl. The compound is acyclic or has a 7-membered heterocyclic ring when J and K are taken together. Said ring is further substituted with O, S, SO or SO₂.

Instant claim 6 recites

“A pharmaceutical composition which comprises:
(i) an effective amount of a compound for treating alopecia or promoting hair growth in an animal in need thereof, wherein said compound is of formula II...
(ii) a second hair revitalizing agent; and
(iii) a pharmaceutically acceptable carrier.”

In claim 6 the compound of formula II is an N linked ketone or diketone when E is O. The compound is either an ester or amide, depending on whether A is O, NH or N-

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(C₁ –C₄) alkyl. The compound is acyclic or has a 7-membered heterocyclic ring when J and K are taken together. Said ring is further substituted with O, S, SO or SO₂.

Instant claim 8 recites

“A pharmaceutical composition which comprises:

(i) an effective amount of a compound for treating alopecia or promoting hair growth in an animal in need thereof, wherein said compound is of formula IV...

(ii) a second hair revitalizing agent; and

(iii) a pharmaceutically acceptable carrier.”

In claim 8 the compound of formula II is an N linked ketone or diketone when E is O and V is N. The compound is either an ester or amide, depending on whether A is O, NH or N-(C₁ –C₄) alkyl. The compound is acyclic or has a 7-membered heterocyclic ring when J and K are taken together. Said ring is further substituted with O, S, SO or SO₂.

In Application Serial No. 09/879,888 claim 17 recites

“A pharmaceutical composition which comprises”

(i) an effective amount of a nitrogen-containing heterocyclic compound having two or more heteroatoms, wherein said compound has a substituents –C(W)-C(Y)- which is attached to a nitrogen atom of the heterocyclic ring,

wherein W and Y are independently selected from the group consisting of O, S, CH₂ and H₂, and

wherein said compound is additionally substituted with a ester or amide substituents attached to any atom of the heterocyclic ring other than said nitrogen atom,

provided that said ester or amide substituents is not an N-oxide of an ester or amide and further provided that said amide substituents is linked to the heterocyclic ring with a carbon-carbon bond:

(ii) a second compound for treating alopecia or promoting hair growth; and

(III) a pharmaceutically acceptable carrier.”

Dependent claims 21, 23, 32 recite that the compound optionally is a 7-member heterocyclic ring.

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The instant claims would be obvious to one of ordinary skill in the art in view of '888, since both applications recite a composition comprising (i) a first compound which is an N linked ketone or diketone, when instant M is O, and W and Y of '888 is O; V of '888 is N; both compounds are either an ester or amide, depending on whether instant A is O, NH or N-(C₁ –C₄) alkyl, both compounds are acyclic or have a 7-membered heterocyclic ring when instant J and K are taken together and the instant application has two or more heteroatoms when the ring is further substituted with O, S, SO or SO₂.

Furthermore, the instant application recites (ii) a second compound for revitalizing hair and '888 recites a second compound for treating alopecia or promoting hair growth. It would be obvious to one of ordinary skill in the art that the intent of the phrases "revitalizing hair" and "treating alopecia or promoting hair growth" are the same, since in the instant application the second compound is paired with a first compound having the intent to treat alopecia.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted that there is no obviousness-type double patenting over 09/781,487, since when compound (i) of the instant composition contains a heterocyclic ring, the ring is 7-membered; whereas the first compound in the composition of '487 is a six-membered heterocyclic ring.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (703) 308-4724. The examiner can normally be reached on Monday through Thursday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


REBECCA COOK
PRIMARY EXAMINER
GROUP 1200/614

December 11, 2003